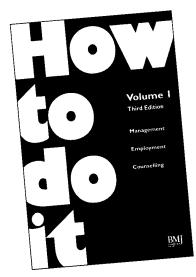
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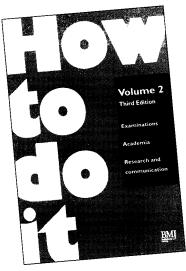
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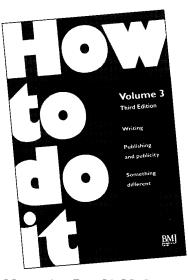
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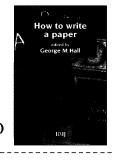
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Uses: Active immunisation against infections caused by hepatitis B virus.

Dosage and administration: For intramuscular use only. Shake well and inspect before use. Three doses should be given, the second one month and the third six months after the initial do: For more rapid immunisation the third dose can be given tw months after the initial dose with a booster at 12 months. Adults and children over 12 years: 20 micrograms (1 ml) give

intramuscularly. Neonates and children 12 years and under: 10 microgram

(0.5 ml) given intramuscularly.

Administer in the deltoid region, though the antero-lateral this is the preferred site for infants. 'Engerix B' should not administered in the buttock since this may result in low immune response. In neonates of HBsAg positive mothers, gi hepatitis B immunoglobulin at the same time as vaccine different sites within a few hours of birth.

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Precautions: Response may be impaired in renal dialysis patients or those who are immunocompromised. Adrenaline 1:1000 should be available in case of anaphylaxis. Use in pregnancy: see Data Sheet.

Adverse reactions: Mild transient local soreness, erythema and induration at the injection site. Occasionally low grade fever, malaise, fatigue, arthralgia, arthritis, myalgia, headache, dizziness, syncope, nausca, vomiting, diarrhoca, abdominal pain, lymphadenopathy, abnormal liver function tests, rashes rarely with urticaria. Exceptionally, severe skin disorders such as erythema multiforme. Very rarely one week or more after

injection, transient arthralgia, pruritus or urticaria, but no causal relationship established.

Neurological manifestations in temporal association with the vaccine, including very rarely paraesthesia and extremely rarely paralysis, neuropathy and neuritis (including Guillain-Barré syndrome, optic neuritis and multiple sclerosis). No causal relationship established.

Early onset allergic-type reactions reported rarely. Legal category POM. 11.8.94.

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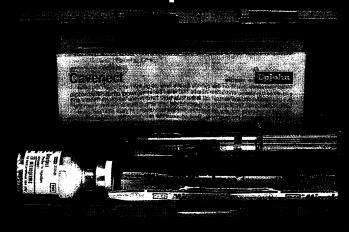
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Dosage and Administration Diagnosis: 5-10 micrograms where there is evidence of neurologic dysfunction.

20 micrograms in other cases. Treatment: neurogenic dysfunction - initial dose 1.25 micrograms. Second dose 2.5 micrograms, and subsequent incremental increases of 5 micrograms until an optimal dose is achieved. Non-neurogenic dysfunction - initial dose 2.5 micrograms. Second dose 5 micrograms. Second dose 5 micrograms for partial response and 7.5 micrograms in for response. Subsequent increments 5-10 micrograms until optimal dose achieved. If no response, next higher dose can be given in 1 hour; if partial response there must be at least a 1-day interval. The usual dose is 10-20 micrograms. Maximum dose 60 micrograms. The recommended frequency of injection is no more than once daily and no more than three times weekly.

The first injection of alprostadil must be done by medically diagnostic tests in the diagnosis of erectile dysfunction

trained personnel. After proper training and instruction, alprostadil may be self-injected. The dose should provide the patient with an erection that is satisfactory for sexual intercourse. It is recommended that the dose administered produces a duration of the erection not exceeding one hour.

Contra-indications, warnings, etc Contra-indications: Known hypersensitivity to alprostadil, benzyl alcohol, or any of the other constituents. Sickle cell anaemia or trait, multiple myeloma, or leukaemia (risk of priapism). Patients with a penile implant or anatomical deformity of the penis such as angulation, cavernosal fibrosis, or Peyronie's disease. Warnings: Prolonged erection and/or priapism. Patients with an erection lasting 4 hours or more should report to a physician for consideration of detumescent therapy. Painful erection is more likely to occur in patients with anatomical deformations of the pens. Regularly follow-up to

detect penile fibrosis. Discontinue treatment where penile angulation, cavernosal fibrosis, or Peyronie's disease develops. Patients on anticoagulants such as warfarin or heparin may have increased propensity for bleeding after the intracavernous injection

Diagnose and treat underlying medical causes of erectile dysfunction before using Caverject.

Use of intracavernous alprostadil offers no protection from the

transmission of sexually transmitted diseases. Individuals should

be counselled about the spread of sexually transmitted diseases,

Pregnancy and lactation. Not applicable. (High doses of alprostadil (0.5 to 2.0 mg/kg subcutaneously) had an adverse

effect on the reproductive potential of male rats, although this was not seen with lower doses (0.05 to 0.2 mg/kg). Alprostadil did not affect rat spermatogenesis at doses 200 times greater than the proposed human intrapenile dose.)

Side effects: Pain in the penis, mainly mild or moderate in intensity (34%). 3% of patients discontinued treatment due to pain. Haematoma at the site of injection (3%). Prolonged erection (2%); priapism (0.5%). Injection site ecchymosis, penile rash, penile oedema, penile fibrosis (1-1.5%). Other local (eg balantis, injection site reactions, phimosis, venous leak, abnormal ejaculation,) and systemic events (eg urinary urgency or impairment, vasodilatation, hypotension, hypertension, supraventricular extrasystole, dizziness, headache, pelvic pain) were reported by fewer than 1% of patients. Interactions: None known. Not intended for co-administration

with any other agent for the treatment of erectile dysfunction Incompatibilities: Not known. Only the supplied diluent should be used to prepare solutions.

Pharmaceutical precautions Caverject must be stored in a

refrigerator until dispensed. May then be stored below 25°C for up to 3 months. Reconstituted solutions should be used

immediately and not stored. Do not store the unused pack or reconstituted solution in a freezer.

Legal category POM

Package quantities Single packs containing a vial of Caverject
powder and a syringe of diluent.

Product licence numbers

PL 0032/0203 Caverject Powder for Injection 10 micrograms PL 0032/0188 Caveriect Powder for Injection 20 micrograms PL 0032/0193 Bacteriostatic Water for Injections diluent

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Reference: Schramek P et al., Br J Urol 1990; 65: 68-71

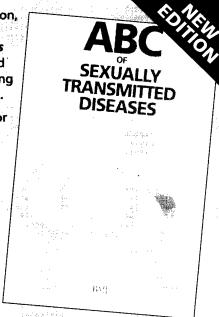
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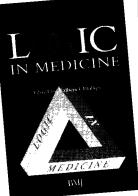
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